OFFICE OF SPECIAL MASTERS

No. 04-1725V

(Filed: August 1, 2006)

JOSEPH WILLIAMS, Petitioner, v. SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent.	*	To Be PUBLISHED Hepatitis B, Lupus, Significant Aggravation

Ronald Homer, Esq., Boston, Massachusetts, for Petitioner.
Ann Donohue, Esq., United States Department of Justice, Washington, D.C., for Respondent.

ENTITLEMENT RULING[1]

On 1 December 2004, a petition for compensation under the National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act)[2] was filed by Petitioner alleging that he suffered a vaccine-related injury following the administration of a Hepatitis B vaccination on 15 May 2002.

The Court conducted an evidentiary hearing in this matter on 7 October 2005 which was followed by written argumentation. The record is now ripe for a decision.

The Vaccine Act authorizes the Office of Special Masters to make decisions on petitions which shall include findings of fact and conclusions of law. §12(d)(3)(A)(I).

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[1] Petitioner is reminded that, pursuant to 42 U.S.C. § 300aa-12(d)(4) and Vaccine Rule 18(b), a petitioner has 14 days from the date of this decision within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire decision" may be made available to the public per the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

[2] The statutory provisions governing the Vaccine Act are found in 42 U.S.C. §§300aa-10 *et seq*. (West 1991 & Supp. 1997). Hereinafter, reference will be to the relevant subsection of 42 U.S.C.A. §300aa.

I. FINDINGS OF FACT

This Court may not rule in favor of a petitioner based on his asseverations alone. Rather, a petitioner's claims must be substantiated at the very least by medical records or by medical opinion. § 13(a)(1). Therefore, the Court turns first to the medical records filed in the above captioned case.

A. Medical Records

On 15 May 2002, the Petitioner, then a fifty-year-old volunteer first responder for the local fire department, received his first and only Hepatitis B vaccination at the Modoc County Health Department.[3] Petitioner's Exhibit ("Pet. Ex.") 2 at 3.

> On 3 June 2002, Petitioner returned to the health department where he complained of: having been bothered by joint pains and swelling that began the morning after his first Hepatitis B vaccination that he received at this health department on May 15, 2002. He stated that the swelling was first in his right hand. The injection was given in the left arm. His wife stated that the swelling started in the left hand. He stated that this swelling and painful joint complaint proceeded to involve both wrists and both ankles and that he experienced some stiffness and difficulty getting out of bed in the mornings. He also stated he had stiffness in his fingers and difficulty closing making a fist. The problem was not as bad at other times during the day. He states that it does not seem to be as severe as it was, but that he and his wife are wondering if it might have had anything to do with the Hepatitis shot he received.

Pet. Ex. 2 at 6. The nurse completing the Immunization Incident Report, Linda Nelson, R.N., advised Petitioner to seek medical attention.

Hence on 4 June 2002, Petitioner presented at the Modoc Medical Center complaining of a "reaction from Hep B shot. Joints are swollen [and] hurt." Pet. Ex. 15 at 1. Dr. Valeska Armisen noted a history of "allergic reaction (swelling of injection site) after Hep B shot 5/15/02. Now [without] swelling joints [illegible] - knees - wrists [symptoms] only started after shot[.] Joint pain worse in morning better with [movement]." Pet. Ex. 15 at 1. His impression was "Bilateral joint pain" and "Arthritis." Id. Labs ordered by Dr. Armisen, however, while revealing an elevated sedimentation rate, which points to a possible inflammatory process, they were negative for a rheumatoid factor indicative of rheumatoid arthritis. Id. at 26-27.

Not satisfied with the care and medicines prescribed by Modoc Medical Center, on 12 June 2002, Petitioner sought treatment at the Canby Medical Center in Canby, California. There he saw Dr. Donna Jones who notes,

He received a hepatitis B shot and with in [sic] 4 hours of receiving the shot he

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[3] Petitioner had no medical insurance and lacking the financial wherewithal primarily sought medical care through the Department of Veterans Affairs ("VA"),for his service in the Vietnam War, or at local county health clinics. See Tr. at 7-8.

> developed left arm swelliing [sic]. Later in the day he began to be affected in his right arm, his knees, and eventually his whole body. He received this injection about 28 days ago and comes in today stating that he is still having swelling, generalized malaise and aching; joint stiffness and difficulty walking. He is concerned because he has no energy and he "hurts everywhere."

Pet. Ex. 4 at 25. The Petitioner indicated to Dr. Jones that he had been prescribed the pain medication Celebrex vis-a-vis the diagnosis of arthritis but that such was not working. However, from other contemporaneous records, it is unclear whether he actually took this medication. Pet. Ex. 2 at 4-6. On examination, Dr. Jones noted that Petitioner's range of motion in his extremities was normal but apparently painful. Yet, she noted no active inflammation, ankle swelling, pitting edema, or foot deformity. Pet. Ex. 4 at 27. Her diagnoses included "delayed hypersensitivity to hepatitis vaccine" and "arthritis, allergic (general)." Id. at 28. She reported the same in an occupational injury report, "Hyposensitivity reaction to Hep vaccine" Id. at 24. Dr. Jones continued Petitioner on Celebrex but also added steroid treatment and, at Petitioner's request, ordered a complete Hepatitis profile. Pet. Ex. 4 at 20. Those tests were negative for Hepatitis A antibody, Hepatitis B surface antigen and antibody, Hepatitis B core antibody, and Hepatitis C antibody. Id. at 37. Dr. Jones ordered a battery of other tests that will be discussed infra. Id. at 33-36.

On 26 June 2003, Nurse Nelson filed a report through the Vaccine Adverse Event Reporting System (VAERS) which described "joint pain [and] swelling that began the morning after the first Hep B in a series of three required for job as vol. fire dept. worker[.] The vaccine was given May 15 [and] symptoms not reported until June 3, 02. [Prescribed] Celebrex, but would not take[.] Seen [at] another provider[.] Hep B panel neg[ative] put on prednisone x 6 days (June 6, 02)." Pet. Ex. 2 at 4.

Petitioner was seen by Dr. Jones on 26 June 2002 for "follow-up on his vaccine reaction." Pet. Ex. 4 at 21. Dr. Jones notes that Petitioner was "generally much improved." Id. at 23. The same was reported at a follow-up appointment on 3 July 2002, at which time Dr. Jones noted "patient continues to improve on the steroids." Pet. Ex. 4 at 17. At that visit it was also noted that Petitioner is now taking Vasotec to combat high blood pressure, a condition with which he had struggled for many years. Her diagnoses now read "1. Unspecified adverse effect of drug medicinal and biological substance, not elsewhere classified" and "2. Arthritis, allergic, multiple sites (nonspecific)." Pet. Ex. 4 at 17.

In the early morning of 16 August 2002, Petitioner went to the emergency room of Modoc Medical Center with "tongue grossly swollen" and difficulty swallowing, which was diagnosed as angiodema.[4] Pet. Ex. 3 at 1. He was treated and released but later that morning presented at the Canby Family Practice. There he saw a Dr. Musselman who noted that Petitioner had been seen by the hospital for swelling on the left side of his face including his lips and tongue. The doctor

[4] Angiodema is "a vascular reaction involving the deep dermis or subcutaneous or submucosal tissues, representing localized edema caused by dilation and increased permeability of capillaries, and characterized by development of giant wheals." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 83.

continues, "This is a patient of Dr. Jones' whose [sic] had serum sickness and allergic reaction . . . It all started when he had a Hepatitis shot on 5-15-02. He developed acute shot reaction and edema. On his labs he has an ANA of 1:5000." Dr. Musselman transferred Petitioner to Redding Medical Center for evaluation of the angiodema and for evaluation by a rheumatologist. Pet. Ex. 4 at 3. It is unclear to the Court why Dr. Jones did not make much of the positive anti-nuclear antibodies ("ANA") test, which was of significance to her colleague and many others, or of the other problematic test results which will be discussed infra.

Hence, on 16 August 2002, Petitioner was seen in an outpatient capacity for the angiodema with tongue swelling, which was thought to be related to the Vasotec blood pressure medication. Pet. ex. 9 at 7. The doctor noted the patient's history including the vaccine and "[t]here is a report in the packaged literature with the Hepatitis B vaccine of delayed serum sickness-type reaction causing arthritis. This is often self-limited and short-lived. No mention is made of diagnosis or treatment. I will have to look into the literature" and "probable adverse reaction to hepatitis b vaccine." Id. Based on this assessment, Petitioner was converted to inpatient status and referred to a rheumatologist, Dr. Timothy Peters for "Arthritis and possible connective tissue disorder." Pet. Ex. 9 at 9, 23.

The history taken by Dr. Peters is quite thorough and notes that, according to Petitioner, his problems began shortly after the Hepatitis B vaccination on 15 May 2002 at which time he developed "swelling in multiple joints" that started in his left arm and spread from there. Dr. Peters notes how rheumatoid arthritis had at first been suspected but potentially discredited by the negative rheumatoid factor, how the course of steroid treatment had been helpful in many respects but had not resolved Petitioner's complaints, and how Petitioner had lost a great deal of weight in the intervening months going from 310 to 234 pounds. Id. Dr. Peters also noted, "He has had chronic lower extremity nodular lesions and a few also on the back and an ulcer that is chronically located over the left [ankle]. He has been told that this is due to agent orange exposure while he was a soldier in Viet Nam in the 1960's. He is followed through the VAMC for this. However, none of these lesions have been biopsied." Pet. Ex. 9 at 24.[5]

On exam, Dr. Peters did note "hyperpigmented nodules scattered" over the lower back and lower extremities as well as healed ulcers particularly in the left lower extremity along with a "left lateral malleolus ulcer" (on the left ankle). Id. at 26. Dr. Peters also noted that certain lab results were significant for a high titer anti-nuclear antibodies ("ANA") at 5120, a Lyme IgG "positive at 1:256" and evidence of lymphopenia/leukopenia.[6] Id. at 27. See Pet. Ex. 4 at 33-36.

Based on his examination coupled with the lab results, Dr. Peters suspected "a connective

[5] In 2000, the Veteran's Hospital scheduled a biopsy of those lesions; however, Petitioner neglected to follow through on that test.

[6] Leukopenia is "reduction in the thember of leukocytes in the blood," and lymphopenia also known as lymphocytopenia is "reduction in the number of lymphocytes in the blood." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 1022, 1078.

tissue disorder along the lines of systemic lupus initially."[7] Id. at 27. At that time he also noted that the apparent skin lesions might be pyodermagangrenosum.[8]

On discharge from hospital, the diagnosis read as follows: 1) probable lupus, 2) angiodema secondary to Vasotec, 3) hypertension and 4) "Iron-deficiency anemia and pancytopenia[9]." Pet. Ex. 9 at 5. On discharge the doctor noted that Petitioner's hepatitis B antibody titer was low despite the recent vaccination. Pet. Ex. 9 at 6; but see Transcript, 7 October 2005, ("Tr.") at 52.

Petitioner followed up with Dr. Jones on 19 August 2002 two days after discharge from the hospital. According to that record, while hospitalized, "the patient was evaluated by rheumatologist and was told that he probably had [systemic lupus erythematosis[10] or "SLE"] most likely triggered by the vaccine." Pet. Ex. 4 at 10. According to Dr. Peters' notes, however, "I am not sure about the relationship (if any) of the hepatitis vaccine with the onset of his disease." Pet. Ex. 5 at 2.

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[7] At trial, Respondent's expert, Dr. Alan Brenner, described Lupus in the following manner:

> Lupus, the best way to define it is an immunologic condition, where the immune system appears to be reacting against antigenic particles that are primarily from the nuclei of our cells. It's our DNA and several other nuclear particles that appear to be participating.
>
> Lupus is a classic medical immune complex disease. When these antigen antibody complexes get together, and they deposit in what I call filter areas -- the smallest of blood vessels; the little blood vessels in the joints, the little blood vessels in the skin, the little blood vessels in the kidney, the lungs, the central nervous system. That's why Lupus is a disease of protein manifestations.
>
> Anyway, wherever they deposit in any given patient then, the different antigens may determine some of where they deposit in any given patient. They elicit a local inflammatory response by fixing components of the inflammatory helper system called the Compliment System.
>
> It looks like Lupus begins because one part of the immune system goes a bit haywire, and over-produces antibodies against these nuclear factors.

Transcript, 7 October 2005 ("Tr.") at 38-39.

[8] Pyodermagangrenosum is "a rapidly evolving, idiopathic, chronic debilitating skin disease that usually accompanies a systemic disease." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 1551.

[9] Pancytopenia is a "deficiency of all cellular elements of the blood." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 1356.

[10] Systemic Lupus Erythematosus is defined as:

> a chronic, remitting, relapsing, inflammatory, often febrile multisystemic disorder of connective tissue, acute or insidious in onset, characterized principally by involvement of the skin (*cutaneous l. erythematosus*), joints, kidneys, and serosal membranes. It is of unknown etiology, but is thought to represent a failure of regulatory mechanisms of the autoimmune system, as suggested by the high level of numerous autoantibodies against nuclear and cytoplasmic cellular components. It is marked by a wide variety of abnormalities, including arthritis and arthralgias, nephritis, central nervous system manifestations, pleurisy, pericarditis, leukopenia or thrombocytpopenia, hemolytic anemia, elevated erythrocyte sedimentation rate, and positive LE-cell preparations.

DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 1072.

Petitioner next saw Dr. Peters on 30 August 2002. At that time, the doctor noted that Petitioner was doing better with occasional "aches and pains." Id. His assessment is "unequivocal SLE with arthritis, leukopenia/lymphopenia, positive ANA, positive double stranded DNA, mild hypocomplementemia[11]. I think the diagnosis is clear. Prognosis is good without major organ involvement." Pet. Ex. 5 at 2. Doctor Peters further indicated "I do wonder if the nodular/ulcerative lesions on his lower extremity have anything to do with the lupus." Id. Adding to the doctor's suspicions is the fact that the lesions cleared up on the steroid treatment. Id.

On 29 August 2002 in conjunction with a claim for worker's compensation. Petitioner was evaluated by Dr. Donald Downs, a Qualified Medical Evaluator in the fields of occupational and sports injuries, with the Sacramento Knee & Sports Medicine Corporation. Pet. Ex. 7 at 14. In taking Petitioner's history, Dr. Downs adds, "He associates the onset of his symptoms with receiving the hepatitis B shot. He implies quite strongly that his treating physicians feel this is also causative." Pet. Ex. 7 at 15. Dr. Downs reviewed no laboratory or diagnostic records; further, he had only partial medical records on hand. Id. Regardless, Dr. Downs opines "his musculoskeletal disability secondary to his arthralgias and myalgias is reasonably medically probable to have been an adverse reaction to the hepatitis B vaccine." Id. at 17. As to the basis for this opinion, Dr. Downs indicates:

> Mr. Williams presents as a somewhat moderate historian, but in the records that I have and his verbal report to myself, he presents a consistent clinical history of initially a local, then very rapidly a generalize [sic] reaction to the hepatitis B vaccine. These types of reactions occur rarely, but are described and in absence of documentation of pre-existing rheumatologic disease, it is reasonable that Mr. William's reaction is secondary to the injection with the information that I have at this point.
>
> The opinions expressed in this report were based upon the history presented by Mr. Williams, his physical examination and the limited records made available.

Id.

The doctor indicated that access to the complete medical records may result in an alteration of his opinion. Hence, he was later presented with additional records including those from the hospital visit on 16 August 2002. Based on these records, he notes:

> The information provided in these records does indicate reason for the assignment for the diagnosis of lupus being a very high ANA as well and elevated sedimentation rate. Again, the association with hepatitis B vaccine is documented in the records. This is a very unusual reaction if it is related to the hepatitis B vaccine and frankly the best opinion that I can render is that it is possible that Mr. Williams' autoimmune disorder was triggered by the vaccine. It is based upon the history presented by Mr. Williams given the onset of symptoms being associated directly with a vaccine that industrial causation of his autoimmune disorder may be reasonable. However, I would suggest that a more expert opinion may come through

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[11] Hypocomplementemia is defined as "abnormally low levesls of complement in the blood" DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 893.

a sophisticated rheumatologist or immunologist.

Pet. Ex. 7 at 6. However, after reviewing yet another set of records, Dr. Downs indicates that the information provided therein did not change his original opinion. Rather, "The information provided in these records tends to support Mr. Williams' arthralgias and myalgias[12] being secondary to an adverse reaction to the hepatitis B vaccine." Pet. Ex. 7 at 2

Perhaps based on Dr. Downs' assessed need for the opinion of an immunologist or rheumatologist, the Petitioner was sent to Dr. Stephen Nagy, an allergist and immunologist, for yet another workers' compensation evaluation.[13] Dr. Nagy saw Petitioner on 11 November 2002. His history is as complete as any proffered in this case. Pet. Ex. 8 at 8-9. In conducting his evaluation and investigation, Dr. Nagy researched the medical literature "on the association of hepatitis B immunization with the initiation/exacerbation of connective tissue disorders; there is considerable controversy as regards the possible association of a hepatitis B immunization either initiating a connective tissue disorder, including lupus, and/or exacerbating an undiagnosed case of same, i.e. lupus." Pet. Ex. 8 at 10. Yet, even so, Dr. Nagy reaches the following conclusion, the pertinent paragraphs of which are reprinted here in full:

> In my opinion, the immunization with hepatitis B which was given to the claimant in the left upper arm on 5/14/02 [sic] either initiated *de novo* a lupus-like syndrome, or exacerbated an undiagnosed connective tissue disorder. In either case, this is an occupational-related illness. The most persuasive aspect of the history is the fact that within hours of the immunization he developed an obvious immunologic response manifested by local swelling/erythema which progressed to the illness as defined over the ensuing four months. Although there is still controversy in the literature as regards an association between all immunizations and connective tissue disorders, there are any number of cases of lupus-like syndromes being associated with a hepatitis B immunization. Furthermore, hepatitis B itself can be associated with arthritis/arthralgia. Lastly, the claimant's medical history prior to the hepatitis B immunization in question is virtually nonexistent. For the previous 20 years he states he was quite well; he only visited a physician at the Reno VA on two occasions for mild hypertension.
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> The nature of this patient's current illness is still not clear; although Dr. Peters, his rheumatologist, feels he has unequivocal lupus, I feel the abnormalities associated with his illness are primarily laboratory; that is, he had an elevated sedimentation rate/double-stranded DNA; on the other hand, he does not have any of the end-organ involvement that we commonly associate with lupus; there is no evidence of major hypertension/renal disease/liver disease/muscle disease, nor does

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[12] Arthralgia is defined as "pain in a joint" and myalgias as "pain in a muscle or muscles." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 249, 1205.

[13] The referral letter indicates that Mr. Williams asserts that he had been given the Hepatitis B vaccine years ago while in the military. Pet.. Ex. 8 at 1. However, that claim is lacking in other more medical histories, and the Court certainly cannot find more likely than not that such occurred.

> he have any evidence of true arthritis; he primarily experiences arthralgia. I feel the problem of weakness/muscle wasting is secondary to a steroid myopathy[14] secondary to the large amounts of steroids with which he has been treated over the last four months. It is possible that this represents an unusual connective tissue disorders, i.e. overlap syndrome, [illegible] could be a manifestation of a persistent serum sickness reaction. If this is, in fact, the diagnosis, the prognosis is much more optimistic as the illness could gradually clear spontaneously over the course of 6-12 months.

Pet. Ex. 8 at 10. However, even to Dr. Nagy, "It was really unclear why he did not seek medical attention" soon after the problems allegedly manifested. Id.

Nearly two years later, Petitioner was again seen for a workers' compensation evaluation, this time by Dr. Adam Duhan with the Evaluation Resource Group. Dr. Duhan states, "Certainly, as reported by numerous treating physicians, taking the Hepatitis B vaccine triggered his Lupus." Pet. Ex. 13 at 67.

Petitioner remains under the care of Dr. Peters and Dr. Jones. But according to Petitioner's affidavit, he continues to suffer from the alleged vaccine-related injuries which manifested four hours after onset. See Pet. Ex. 10 at 3; Pet. Ex. 19 at 2-3; Pet. Ex. 13 at 67, 100; and Pet. Ex. 21 at 9. Moreover, on 25 November 2003, Dr. Jones wrote in a letter regarding Mr. Williams' workers' compensation claim that he would "never be able to return to active work" due to "ongoing problems as a result of his reaction to hepatitis B and ensuing systemic lupus that he had because of it."

B. Medical Opinion

As noted supra, a petitioner may substantiate his claim either via the medical records or medical opinion. And, in fact, the Vaccine Act adjures this Court to consider any diagnosis, conclusion, medical report or impression contained in the record. However, that being said, the act says quite explicitly that these "shall not be binding on the special master" but must be considered based on the entirety of the record and the course of the injury. § 13(b)(1). Therefore, while this Court has always shown appropriate deference to the opinions, impressions, or diagnoses of treating physicians and other medical experts, that is not to say that such are binding on the Court. Moreover, this Court has the obligation, in light of the "gatekeeping" function required by Daubert v. Merrow Dow Pharm. Inc., 509 U.S. 579, 597 (1993), to assess the reliability of medical or scientific opinion or testimony. See, Terran v. Secretary of HHS, 195 F.3d 1302, 1316 (Fed. Cir. 1999); see also Ryman v. Secretary of HHS, 65 Fed. Cl. 35, 40 (a special master acts properly as a gatekeeper when he"determines whether expert testimony may be admitted, credited, or otherwise relied upon.") Bearing this in mind, the Court now turns to the medical opinions proffered in this case.

In addition to those opinions proffered as part of the evaluation cited supra, Petitioner proffered additionally the live testimony of Dr. Nagy, a long-time professor at the University of

[14] Myopathy is "any disease of a muscle." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 1215.

California's Davis campus and who is board certified in internal medicine and allergy immunology. Tr. at 6. Respondent, offered the testimony of Dr. Alan Brenner, who is board certified in internal medicine and immunology and has practiced for more than three decades as a clinical rheumatologist.

At the hearing, Dr. Nagy opined that the Hepatitis B vaccination administered on 15 May 2002 initiated a connective tissue disorder within four hours of the administration. According to Dr. Nagy, the cause of lupus or other connective tissue disorders has to do with a certain genetic or underlying susceptibility coupled with an environmental trigger. He readily acknowledged that "most of the time" the trigger is unidentifiable. Tr. at 36. However, in this particular instance, Dr. Nagy believes the trigger to have been the Hepatitis B vaccination.

> According to Dr. Nagy:
> Well, the most persuasive aspect of this is the history. I mean, the illness begins within four hours of getting that injection, and progresses inexorbitently to a classical -- what I won't call serum sickness -- but a classical antigen antibody mediated reaction with swelling, fever, joint aches, and so forth -- to three weeks later, where the man has developed, essentially, laboratory evidence of a major connective tissue disorder. But that's the most persuasive aspect.

Tr. at 16-17.

During the hearing, the crux of the argument did not center on the question of whether Hepatitis B vaccination can trigger a connective tissue disorder. Rather, Respondent's expert, Dr. Alan Brenner, explains that there is a theory posited whereby Hepatitis B antibodies, produced as a result of the first or second vaccine administration for instance, given the right conditions, may interact with Hepatitis B antigen from the second or third administration, thereby forming antigen antibody complexes that can wreak all sorts of mischief. Tr. at 57. The difficulty in this particular case, according to Dr. Brenner, is the timing of onset. It takes time for the immune system to react to the Hepatitis B antigen introduced by the vaccination thereby creating Hepatitis B antibodies. This process usually takes "days and days" or two to three weeks. Tr. at 50-52. And the timing of this process is borne out in the anecdotal literature and case studies. Respondent's Exhibit ("R. Ex.") I at 131; see also R. Ex. A at 8. Moreover, argued Dr. Brenner, it is virtually always the case that these reactions take place only after the second or third administration of Hepatitis B, because it is a rather weak vaccine – and hence the need to administer it in a series of three shots. Dr. Nagy agreed with this timing in general but pointed to one anecdotal report, and that in a letter to the editor and not in a peer reviewed portion of the medical journal, where a connective tissue disorder was noted within two weeks after the first administration of Hepatitis B. Tr. at 13-14; Pet. Ex. 32. However, according to Dr. Brenner, "[I]t would be very, very unusual to have any sort of chronic immunopathy or chronic immune process that began four hours after vaccination. You know, it defies logic. It even defies the literature that's out there." Tr. at 45.

In order to account for Petitioner's unusually fast onset, Dr. Nagy presumes that Hepatitis B antibodies must have already been present. Tr. at 34. It is possible, explains Dr. Nagy, given

Petitioner's history, he may have contracted the disease during the course of his life and in particurlar during a tour to Southeast Asia courtesy of the United States government and international Communism. Dr. Nagy acknowledges that, despite testing done both contemporaneously and after a period of time, no evidence was ever found of Hepatitis B antibodies. But, says Dr. Nagy, the antigen antibody complex reaction post-vaccination may have "used up" those antibodies and, furthermore, argues Petitioner, subsequent medical treatment may have suppressed their later resurgence.

The Court finds Dr. Nagy's explanation speculative at best. Concerning factual findings, it is required that a special master, "believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the [special master] of the fact's existence." In re Winship, 397 U.S. 358, 371-72 (1970) (Harlan, J., concurring). Moreover, mere conjecture or speculation does not meet the preponderance standard. Snowbank Enterprises v. United States, 6 Cl. Ct. 476, 486 (1984).

Dr. Nagy's theory hinges on the existence of a fact, in this case that Hepatitis B antibodies were present prior to the 15 May 2002 vaccination, the burden of which is Petitioner's to prove. It must be noted that a test for Hepatitis B core antigen was never conducted. Tr. at 44. However, in this instance, there is no evidence in the medical records that Hepatitis B antibodies were present prior to the injection or have ever been present since and this despite three separate tests that were conducted both contemporaneous to the event and many months out. Petitioner argues that the reaction itself is evidence that he must have had Hepatitis B antibodies preceding the vaccination. The Court cannot accept this tautological argument.

Dr. Brenner, on the other hand, acknowledges that Mr. Williams suffered "an acute reaction, which is probably allergic mediated" within four hours of the vaccination; however, he cannot conjure a theory or "understand the mechanism" whereby such a reaction could cause the a chronic immune process. Such a phenomenon "defies logic" and "defies the literature that's out there." Tr. at 44-45. And Dr. Nagy likewise acknowledges that the Petitioner "allegedly could have had some sort of unusual allergic reaction. But that subsides within four to six hours, and there's no residual from that sort of thing." Tr. at 35. Of course, as discussed supra, Dr. Nagy thinks it more likely to have been "the initiation of an immune complex disease." Id.

The following exchange with Dr. Brenner is instructive:

THE COURT: Something presumably happened to Mr. Williams about four hours after the vaccination. We have a description of the symptomalogy; what happened?

THE WITNESS: Oh, I think that, you know, this sort of reaction has been very well studies [sic] in vaccinology. A four hour time frame for vaccination to acute local reaction is not uncommon. As a matter of fact, it's probably the most common reaction.

You know, I mean literally, any place from minutes to

six to eight hours, it looks like, according to the vaccine literature, it's basically the same immunologic mechanism.

Now what happened next is a whole other question. Because what happens next is muscular skeletal pain. What happens next is not documented in the medical record to represent arthritis. Only in the barest of circumstances, when he was hospitalized in August, did Dr. Peters make any mention of joint problems. That aside, every examination before and every examination subsequent, where joint exam was done, showed no evidence of articular inflammation.

So the real question is, what happened? You know, this has been defined as an Arthritis. But you can't define Mr. Williams' condition as arthritis. In my opinion, that's impossible.

THE COURT: Okay, then, what is it?

THE WITNESS: It's Arthralgia. Then the question becomes, you know, why would an acute reaction, which is probably allergic mediated, then, in and of itself, lead to chronic muscular/skeletal pain? I don't have an explanation for that, because I don't understand the mechanism. It doesn't make sense.

THE COURT: Okay, but I gather from what you're indicating, that the acute reaction that occurred about four hours post-vaccinal, in and of itself was sequela to the vaccination?

THE WITNESS: Well, you know, my only problem is, you know, the idea of having some sort of objective medical record that documents what patients tell us. Having said that, the answer is yes.

Tr. at 43-44.

Dr. Brenner further posits that the allergic reaction occurring four hours post vaccination had nothing to do with Petitioner's latter diagnosed connective tissue disorder; instead, Petitioner had a pre-existing underlying autoimmune disorder for which the chronic ulcerating rash and nodules were a manifestation. In support of this theory Dr. Brenner offers his not insubstantial three decades as a rheumatologist and points to the record of the treating rheumatologist who likewise suspected that the nodules were representative of lupus. Were proper tests conducted before the vaccine was administered, says Dr. Brenner, more likely than not Petitioner would have been diagnosed with lupus at that time.

Puzzled by his nuanced stance, the following exchange occurred between the Court and Dr. Brenner:

THE COURT: Is his condition today significantly worse than what it was prior to the vaccination?

THE WITNESS: I don't know; subjectively, perhaps -- objectively, no. I mean, objectively, the chances are overwhelming. The only

> reason that we see high grade inflammation following vaccination and not before vaccination is because nobody looked before vaccination. So that's the first thing.
>
> The second thing is, we know from recent studies, wonderful studies that have been done, both in Lupus and in Rheumatoid Arthritis, that auto-immune antibodies long precede clinical manifestations of either disease to begin with.
>
> We also know that his high blood pressure, one of his major clinical manifestations, long preceded vaccination or the other problems that he developed. So what he has that's worse is muscular skeletal pain. Now that's a subjective complaint of diverse ideology, likely not Arthritis; likely not on an immune basis.

Tr. at 47.

Petitioner's counsel eventually followed up on this line of reasoning during cross examination:

A He already had Lupus.
Q Now he has Lupus?
A No, he had Lupus then. That's my point.
Q Yes, but he was asymptomatic, aside from the nodules, wasn't he?
A Yes.
Q So wasn't there a significant worsening of symptoms after the Hepatitis B?
A Absolutely.

Tr. at 103-04.

Though Dr. Nagy opined in his written report that the vaccination "either initiated de novo a lupus-like syndrome, or exacerbated an undiagnosed connective tissue disorder," Pet. Ex. 8 at 10, he was quite critical of Dr. Brenner's diagnosis at trial, saying, "[I]f all you're hanging your hat on is some hypertension in a heavy black man and some nodules on his feet, with no other history, I can't believe there's a rheumatologist in America that would accept that as evidence of connective tissue disorder." Tr. at 29. But Dr. Nagy is not a rheumatologist and so may be a poor spokesman for the group. So, for now the Court reserves judgment on whether this condition was from Lupus or some other connective tissue disorder as Dr. Brenner opines or from exposure to Agent Orange as Petitioner himself maintains.

> As far as Dr. Nagy is concerned:
> I felt that the chronology of the illness -- I mean, the onset which it appeared apparently four hours after he received the injection was just this rapid progression, to what now three years later is really a major devastating illness, just spoke to the fact that there had to be an association between the immunization and the illness.

Tr. at 10.

For now, the most the Court is willing to say is that, despite being an overweight and unapologetic, long-term smoker with a history of hypertension and chronic skin ulcers predominantly haunting his lower back and lower extremities, Petitioner appears to have been in relative good health prior to the vaccination and had been physically capable of serving as a volunteer fire fighter, of participating with his sons in a lawn care business, and of being his wife's care-giver for nine years. Four hours after the vaccination we see the onset of issues that eventually led to a diagnosis of systemic Lupus, from which Petitioner has been put on disability and is unable to do those aforementioned activities. To be sure, the diagnosis of Lupus is primarily clinical and somewhat subjective as to the arthralgias and myalgias. But no doubts are raised in the medical records as to whether Petitioner was exaggerating his level of pain, discomfort and other issues related to his condition, including loss of balance and the inability even to write his own name. And most if not all of the contemporaneous medical records note a temporal relationship between the vaccination and the onset of Petitioner's injury with several doctors stating explicitly that they viewed the injuries as sequela to the vaccination.

II. CONCLUSIONS OF LAW

Something happened to Mr. Williams the day of his vaccination. The quandary is whether that something is related to the vaccination, in which case he may be eligible for compensation under this program if the Court can find such by a preponderance of the evidence.

A. Legal Standards

In legal terms, "Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole -

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1) of this title, and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." §13(a)(1).

Concerning §11(c)(1) and certain other preliminary requirements, it is undisputed that (1) Petitioner is a valid legal representative; (2) the vaccine at issue is set forth in the Vaccine Injury Table; (3) the vaccine was administered in the United States; (4) no one has previously collected an award or settlement of a civil action for damages arising from the alleged vaccine-related injury; and, (5) no previous civil action has been filed in this matter. §§ 300aa-11(b) and (c). Additionally, the § 300aa-16(a) requirement that the petition be timely filed has been met.

The dispute rather is whether petitioner can demonstrate that he received an injury recognized by the Vaccine Injury Table, 42 C.F.R. § 100.3, ("Vaccine Table" or "Table") within the statutorily prescribed time period or, in the alternative, that he "sustained, or had significantly aggravated, any

illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in subparagraph (A)." § 11(c)(1)(C)(I) & (ii)(I).

In this particular case, the Petitioner is not claiming a "Table Injury."[15] Therefore, he must demonstrate by preponderant evidence that the vaccination in question, more likely than not, caused-in-fact the alleged injury. Id. If the Petitioner is successful in showing a prima facie case, the burden then shifts to Respondent to prove that the injury or condition "is due to factors unrelated to the administration of the vaccine described in the petition." § 13(a)(1)(B); Whitecotton v. Secretary of HHS, 17 F.3d 374, 376 (Fed Cir. 1994).

1. Causation-in-fact generally

As Dr. Nagy explained, it certainly appears, given the timing, "there had to be an association between the immunization and the injury." Tr. at 10. But this sort of post hoc ergo propter hoc[16] logical fallacy "is regarded as neither good logic nor good law." Fricano v. U.S., 22 Cl. Ct. 796, 800 (1991). The Court cannot infer causation from temporal proximity alone. In fact, it has been held that where a petitioner's expert views the temporal relationship as the "key" indicator of causation, the claim must fail. Thibaudeau v. Secretary of HHS, 24 Cl. Ct. 400, 403 (1991). Rather, a petitioner must explain how and why the injury occurred. Strother, 21 Cl. Ct. at 370. After all, inoculation is not the cause of every event that follows. Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1993), cert. denied, 469 U.S. 817 (1984).

Instead, a Petitioner must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused the injury alleged. See 11(c)(1)(C)(ii)(I) & (II); Grant v. Secretary of HHS, 956 F.2d 1144 (Fed. Cir. 1992); Strother v. Secretary of HHS, 21 Cl. Ct. 365, 369-70 (1990), aff'd, 950 F.2d 731 (Fed. Cir. 1991). The Federal Circuit has indicated that every petitioner must:

> show a medical theory causally connecting the vaccination and the injury. Causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect.

Grant, 956 F.2d at 1148 (citations omitted); see also Strother, 21 Cl. Ct. at 370. Additionally, merely showing an absence of an alternative cause of injury does not meet petitioner's burden of proof. Grant, 956 F.2d at 1149. That being said, where several potential causes present themselves, a petitioner need not show that the vaccination was the sole cause of the injury but may demonstrate that it was a "substantial factor" in causing the alleged injury which would not have occurred "but for" the vaccine. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir.1999).

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[15] Table injuries for Hepatitis B include "Anaphylaxis or anaphylactic shock" within zero to four hours of vaccination and "Any acute complication or sequela (including death) of above event." 42 C.F.R. § 100.3 (VIII).

[16] Latin for "after this, therefore because of this."

However, the Federal Circuit recently articulated an alternative three-part causation-in-fact analysis as follows:

> [Petitioners'] burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Secretary of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). And furthermore, "[R]equiring that the claimant provide proof of medical plausibility, a medically-acceptable temporal relationship between the vaccination and the onset of the alleged injury, and the elimination of other causes-is merely a recitation of this court's well-established precedent." Id. at 1281.

According to the court in Althen, the Vaccine Act anticipates that Petitioners may use circumstantial evidence to prove their claim. A bright line test, like the one criticized in Althen, which required that petitioners provide medical literature in order to prevail, "prevents the use of circumstantial evidence envisioned by the preponderance standard and negates the system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." Id. at 1280. But see, Knudsen, 35 F.3d at 550 (when evidence is in equipoise, the party with the burden of proof failed to meet that burden) and Hines v. Secretary of HHS, 21 Cl. Ct. 634, 646 (1990), aff'd, 940 F.2d 1518 (Fed. Cir. 1991). In other words, even where a medical theory involves "a sequence hitherto unproven in medicine, the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." Althen, 418 F.3d at 1280.

Concerning the framework iterated in Althen, the Federal Circuit recently held that the prongs may overlap. Capizzano v. HHS, No. 00-759V, 2004 WL 1399178 (Fed. Cl. Spec. Mstr. June 8, 2004), aff'd, 63 Fed. Cl. 227 (2004) (Merow, J.), rev'd, No. 05-5049, slip op. at 14 (Fed. Cir. Mar. 9, 2006). Specifically, the Federal Circuit in Capizzano collapsed the second and third prongs for treating physicians who utilize temporal relationship to demonstrate a cause and effect relationship. According to Capizzano, treating physicians "are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" Id. (quoting Althen, 418 F.3d at 1280); see also Zatuchni v. Secretary of HHS, 69 Fed. Cl. 612, 624 (2006). Nevertheless, the Vaccine Act explicitly notes that the opinion or diagnosis of a treating physician is not binding on the Court but rather must be viewed in light of "the entire record and the course of the injury." § 13(b)(1).

As to the third prong in Althen, the Federal Circuit more recently indicated that, even when a Vaccine can cause a particular injury, and particularly where there is more than one potential trigger, the petitioner must still demonstrate an appropriate temporal relationship between the vaccination and the injury alleged. Pafford v. Secretary of HHS, 2006 WL 1679714, slip op. *4 (Fed. Cir. June 20, 2006).

Ultimately, however, there is "no hard and fast rule for what specific, individual elements of

proof a petitioner must present in order to establish a prima facie case of causation-in-fact; the rule is really one of reason, in which the Special Master gives greater weight to certain factors in certain cases depending on the facts of that particular case and the medical developments existing at that time." Pafford v. Secretary of HHS, 64 Fed. Cl. 19, *31 (2005), aff'd, Pafford v. Secretary of HHS, 2006 WL 1679714, slip op. (Fed. Cir. June 20, 2006) (emphasis in original) (citing Knudsen, 35 F.3d at 548 ("Causation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast per se scientific or medical rules.")).

> Moreover, as the Court of Federal Claims opined:
> Indeed, one can imagine a hypothetical case where a completely healthy individual receives a vaccine and suffers some condition shortly thereafter. The Special Master may conclude that, based on the entirety of facts--including the petitioner's relative health prior to the vaccine--the petitioner has satisfied his burden of proof. This might be the case if there is an absence of alternative causes apparent in the record or the biologic mechanism that petitioner demonstrates is particularly compelling.

Pafford v. Secretary of HHS, 64 Fed. Cl. at *31.

As aforementioned, when and if a Petitioner demonstrates a prima facie case of causation-in-fact, the burden of proof then shifts to Respondent to show that the claimant's injuries are "due to factors unrelated to the administration of the vaccine described in the petition." § 13(a)(1)(B); Whitecotton v. Secretary of HHS, 17 F.3d 374, 376 (Fed. Cir. 1994).

2. Significant aggravation specifically

The Vaccine Act also specifies that a Petitioner need not prove a vaccine caused an injury de novo but is entitled to compensation if a vaccination is shown to have "significantly aggravated, any illness, disability, injury, or condition." § 11(c)(1)(C)(ii)(I). Section 33(4) of the Vaccine Act defines the term "significant aggravation" as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health."

> The legislative history further elucidates the meaning of "significant aggravation":
> The committee has included significant aggravation in the Table in order not to exclude serious cases of illness because of possible minor events in the person's past medical history. This provision does not include compensation for conditions which might legitimately be described as pre-existing (e.g., a child with monthly seizures who, after vaccination, has seizures every three and a half weeks), but is meant to encompass serious deterioration (e.g., a child with monthly seizures who, after vaccination, has seizures on a daily basis).

H.R. Rep. 98, 99th Cong., 2d Sess. 15-16 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6356-57.

In Whitecotton v Secretary of HHS, 81 F.3d 1099 (Fed. Cir. 1996) the Court of Appeals for the Federal Circuit announced its test for significant aggravation claims. Id. at 1107. For evaluating

whether a petitioner has made out a prima facie significant aggravation claim under the Act, the special master must:

> (1) assess the person's condition prior to administration of the vaccine, (2) assess the person's current condition, . . . (3) determine if the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination within the meaning of the statute.[17]

B. Legal Discussion

Petitioner claims that the vaccine in question either caused the injury alleged de novo or, in the alternative, significantly aggravated an underlying condition. The Court will examine each in turn.

1. Causation-in-fact

The standard for causation-in-fact presently in ascendance is that articulated by the Federal Circuit in Althen. In order to make a prima facie showing under that holding, a petitioner must demonstrate by a preponderance of the evidence:

(1) a medical theory causally connecting the vaccination and the injury;
(2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and
(3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Secretary of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Turning to the first prong of Althen. The Court must determine whether Petitioner has presented a reputable medical or scientific explanation that causally connects the Hepatitis B vaccination to the injury alleged. See Grant, 956 F.3d at 1184. Based on the testimony taken at trial, it appears that the expert witnesses on both sides agree theoretically that an immunologic reaction – specifically an antigen antibody complex – can cause a myriad of issues including quite plausibly a connective tissue disorder as was experienced by Petitioner. But while this represents a reasonable medical theory in the abstract, it becomes extremely problematic when applied to the facts of this case.

The experts agree that, in general, this sort of antigen antibody complex disorder takes a week or more at least before the first symptoms show and that such injuries typically occur after the second

[17] The Whitecotton decision includes a fourth prong, inapplicable to the present case, that requires the special master to "(4) determine whether the first symptom or manifestation of the significant aggravation occurred within the time period prescribed by the Table." 81 F.3d at 1107.

or third administration of Hepatitis B vaccine. In this particular case, Petitioner alleges that his symptoms began four hours after the first administration of Hepatitis B.[18]

Petitioner's expert attempts to avoid this thorny issue by assuming Petitioner must have already had Hepatitis B antibodies present in his system before the vaccination, thereby allowing for a near-immediate onset of Petitioner's condition. However, as previously indicated, Dr. Nagy's theory relies on an underlying fact that finds inadequate support in the medical records.

That being the case, no evidence has been presented, and perhaps none exists on the face of the planet, that an antigen antibody complex can develop de novo within four hours of one's first Hepatitis B vaccination. This is not to say we are "in a field bereft," but that all scientific and medical knowledge on this subject and the experts who testified at trial actually aver to the contrary. Therefore, the Court finds that Petitioner has not presented a theory that "causally connects" via a logical sequence of cause and effect, the vaccination with the injury alleged in a medically appropriate time frame. Therefore, Petitioner fails all three prongs of the test articulated in Althen.

Post-Althen, the Federal Circuit accorded great weight to the opinions of treating physicians thereby marrying the third prong, temporal relationship, with the second prong, logical sequence of cause and effect. See Capizzano, 440 F.3d at 1317. In the present case, Petitioner identifies numerous doctors who either treated or evaluated him and concluded, some against their fiscal interests perhaps, that his medical issues are causally linked to the vaccination.

Petitioner points to a VAERS report filled out by Nurse Nelson which notes "joint pain [and] swelling that began the morning after the first Hep B in a series of three." Pet. Ex. 2 at 4. However, the nurse's report appears to be a factual recitation rather than a causative opinion. Similarly, while Dr. Armisen records a history of "allergic reaction (swelling of injection site) after Hep B shot 5/15/02," his records are silent as to causation. Pet. Ex. 15 at 1 et. seq.

Dr. Jones with the Canby Medical Clinic is the first treating physician to relate the vaccine to the Petitioner's condition, and she continued to maintain throughout that the Petitioner's injuries were due to an "ongoing problems as a result of his reaction to hepatitis B and ensuing systemic lupus that he had because of it." Her colleague, Dr. Musselman reiterates this assessment. Pet. Ex. 4 at 3. Yet, the court is unaware of any qualification or expertise attributable to Dr. Jones other than as a general practitioner and therefore must weigh her assessment accordingly.

Dr. Musselman sent Petitioner to hospital where he could be evaluated by a rheumatologist. The hospital admission notes indicate "probable adverse reaction to hepatitis b vaccine." Pet. Ex. 9 at 7. Yet, Dr. Peters, the rheumatologist to whom Petitioner is eventually referred concludes, "I am

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[18] Of course, there is the sui generis statement by Petitioner, uncorroborated by any records or tests that he had a prior administration of the Hepatitis B vaccine many years ago pursuant to a sojourn in the Republic of South Vietnam. However, it is the Court's understanding that there was no vaccination for Hepatitis B at that time; though this Special Master did receive a gamma-globulin injection for Hepatitis, presumably Hepatitis A, at that time and perhaps Petitioner did as well.

not sure about the relationship (if any) of the hepatitis vaccine with the onset of his disease." Pet. Ex. 5 at 2. Likewise, Dr. Peters questions whether "the nodular/ulcerative lesions on his lower extremity have anything to do with the lupus. They appear to be healing on steroids." Id. The opinion of Dr. Peters, as a treating rheumatologist, is accorded significant weight. See Capizzano, 440 F.3d at 1317.

In conjunction with a claim for workers' compensation – Petitioner was required to get the Hepatitis B shot in conjunction with his role as a volunteer firefighter – Mr. Williams was evaluated by several doctors.

The first, Dr. Downs, says that Petitioner's "musculoskeletal disability secondary to his arthralgias and myalgias is reasonably medically probable have been an adverse reaction to the hepatitis B vaccine." Pet. Ex. 7 at 17 (emphasis added). But, Dr. Downs is far from unequivocal on the subject. Shown certain additional records, he writes, "This is a very unusual reaction if it is related to the hepatitis B vaccine and frankly the best opinion that I can render is that it is possible that Mr. Williams' autoimmune disorder was triggered by the vaccine. It is based upon the history presented by Mr. Williams given the onset of symptoms being associated directly with a vaccine that industrial causation of his autoimmune disorder may be reasonable. However, I would suggest that a more expert opinion may come through a sophisticated rheumatologist or immunologist."(emphasis added). Pet. Ex. 7 at 6. And after reviewing yet another spate of records, he indicates, "The information provided in these records tends to support Mr. Williams' arthralgias and myalgias being secondary to an adverse reaction to the hepatitis B vaccine." Pet. Ex.7 at 2. Going to the weight of Dr. Down's opinion is that he is neither an immunologist nor a rheumatologist. Instead he is a qualified evaluator of occupational and sports injury claims. As such, his opinion is accorded less weight than that of Dr. Peters and even that of Dr. Jones, a general practitioner but a treating physician. It is unclear whether Dr. Downs, or any of the doctors who evaluated Petitioner for the workers' comp claim, would properly qualify as a "treating physician."

Dr. Nagy, a board certified immunologist, also evaluated Petitioner at the behest of the insurance company. He concludes that, despite a conflict in the medical literature:

> In my opinion, the immunization with hepatitis B which was given to the claimant in the left upper arm on 5/14/02 [sic] either initiated de novo a lupus-like syndrome, or exacerbated an undiagnosed connective tissue disorder. In either case, this is an occupational-related illness. The most persuasive aspect of the history is the fact that within hours of the immunization he developed an obvious immunologic response manifested by local swelling/erythema which progressed to the illness as defined over the ensuing four months.

Pet. Ex. 8 at 10. The problems endemic to Dr. Nagy's theory regarding vaccine causation have been thoroughly discussed supra but center around his "presuming that there was an immediate antigen antibody reaction in that four hours, and it simply initiated a cascade of events which just didn't stop." Tr. at 23. This presumption is premised on a supposition the Court simply cannot accept ipse dixit.

A third doctor who evaluated Petitioner concerning the workers' compensation claim at the

behest of the insurance company, Dr. Adam Duhan with the Evaluation Resource Group, states "Certainly, as reported by numerous treating physicians, taking the Hepatitis B vaccine triggered his Lupus." Pet. Ex. 13 at 67. Again, Dr. Duhan's qualification to opine on the subject is somewhat murky given his letterhead listing as "Occupational/Internal" with the Evaluative Resource Group in Albany, California. As such his opinion is accorded a weight just shy of Dr. Downs.

Therefore, while the medical providers, including the treating physicians Doctors Armisen, Jones, and Peters, are hardly unanimous in ascribing Petitioner's condition to the Hepatitis B vaccination, that sentiment is certainly expressed throughout the records.

As to the medical and scientific literature entered into the record, this Court has long recognized that, while petitioners are not required to submit peer reviewed literature in support of their theory as a prerequisite for proving causation, the plausibility of a medical theory can be bolstered in any number of ways including, but not limited to (1) evidence that at least a sufficient minority in the medical community has accepted the theory as to render it credible; (2) epidemiological studies and an expert's experience, while not dispositive, lend significant credence to the claim of plausibility; (3) articles published in respected medical journals, which have been subjected to peer review, are also persuasive; however, publication "does not necessarily correlate with reliability," because "in some instances well-grounded but innovative theories will not have been published." Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 593-94 (1993). Even so, petitioners are often encouraged to submit such literature where available in order to meet their burden of proof – that the vaccine in question more likely than not caused the injury alleged.

In this particular case, of the extensive literature filed by both parties, only a very few articles were actually referenced at hearing and in the post-hearing briefs.[19] Those articles with few exceptions go to the theory whereby the second or third administration of Hepatitis B vaccination has been temporally, if not causally, linked to connective tissue disorders like Lupus with onset two to three weeks after vaccination. Petitioner notes that one letter to the editor, not subject to peer review, indicated a case where such had developed two to three weeks after the first administration of Hepatitis B. Pet. Ex. 32. In accordance with § 13(b)(1), the Court has reviewed the literature proffered and accorded it an appropriate weight in the final analysis, which is relatively de minimis as none is directly on point with the facts in this case.

Petitioner argues that he "must only show by a preponderance of the evidence that a vaccine, rather than something else, likely caused the injury." Petitioner's Reply to Respondent's Post Hearing Brief at 14. Further, because there is no more likely cause identified in the medical records, ergo the

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[19] Prior to the hearing the parties were reminded of the following:

> The parties are reminded that pursuant to General Order 29 of the United States Claims Court issued 1 July 1991, and amending Appendix J (now Appendix B), Rule 8, of the Rules of the United States Claims Court, any fact or argument not raised specifically in the record before the Special Master shall be considered waived, and cannot be raised by either party in proceedings on review of a Special Master's decision.

Entitlement Pre-Hearing Order, 18 August 2005.

vaccine can be said to have been most likely cause. However, Petitioner misapprehends his burden of proof, which is to show that the vaccine more likely than not caused the injury alleged. A prima facie case of causation-in-fact may be shown by affirmatively meeting the three prongs articulated in Althen and is not met simply by showing an absence of a more likely etiology. Grant, 956 F.2d at 1149.

Petitioner further argues that "in a field bereft of complete and direct proof of how vaccines affect the human body," he may prove his claim via circumstantial evidence. See Althen, 418 F.3d 1274, 1280. Quite so. It is possible that circumstantial evidence may, on the whole, add up to a preponderance. However, the weight accorded that evidence is the demesne of this bench. Furthermore, to the extent that this argument is used to say that modern medicine and science know nothing of how the human immune system works or how vaccine-related injuries may occur, it is patently incorrect and is certainly contradicted by the numerous articles filed and the testimony of the learned experts in this case. Rather, the court in Althen recognized that, given the relative rarity of vaccine-related injuries, a Petitioner ought not be required to present certain types of evidence like epidemiological studies, pathological markers, medical literature and the like, which may or may not exist. Hence, while petitioners may be limited in the type or quality of evidence available, they may yet proffer a quantum of circumstantial evidence including, but certainly not limited to, the opinions of treating doctors, expert opinions, and supportive medical or scientific literature, that – taken as a whole – adds up to preponderant evidence.

Petitioner argues that requiring him to prove the vaccine in question caused the injury alleged, or to prove certain factual suppositions on which his expert's theory is based, is equivalent to requiring proof of a biological mechanism, and according to the Federal Circuit,"[T]o require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program." Knudsen v. Secretary of HHS, 35 F.3d 543, 549 (1994). However, Petitioner is not being required by this Court to propose or prove that a specific biological mechanism can and did cause Petitioner's injury, but he is required via Althen and its predecessors and progeny to proffer a plausible medical theory that causally connects the vaccine with the injury alleged. This he has not accomplished.

Here Petitioner attempts to knit various pieces of circumstantial evidence into the warp and woof of a fabric that supports his burden of producing preponderant evidence, but unlike the fabled thread of Theseus, when a particular thread of Petitioner's evidence is followed, it does not lead to a particular conclusion but instead, the tapestry of their legal argument unravels. Therefore, Petitioner does not prevail under a causation-in-fact analysis.

2. Significant aggravation

That being said, the factual scenario in the present case is particularly prescient. According to the findings articulated supra, Petitioner was asymptomatic prior to the vaccination and afterwards the records document a cascade of medical issues the treatment of which led eventually to a clinical diagnosis of a connective tissue disorder and from which Petitioner has been rendered on disability.

Prior to the vaccine, the Petitioner was physically active as a volunteer firefighter, lawn maintenance provider, and long-time caretaker of his spouse. Afterwards, he could hardly scribe his own name.

At the risk of stating the obvious, either Mr. Williams had the nascent connective tissue disorder prior to the time of vaccination or it developed after the vaccination. Respondent's expert, Dr. Brenner, opines that Petitioner suffered from Lupus prior to the vaccination as evidenced by the long-standing issue of nodules and ulcers around his lower back and lower extremities. Petitioner's treating rheumatologist, Dr. Peters, appears to suggest the same. Per contra, while asseverating such in his written report, Petitioner's expert, Dr. Nagy, offered a pointed critique of this possibility during oral testimony. Tr. at 29.

In the final analysis, considering the case as a whole, the Court finds that Dr. Brenner is more likely than not correct on the matter. His theory has the inferential support of Petitioner's treating rheumatologist. Moreover, Dr. Nagy is by training and practice an immunologist, and while he has seen his share of lupus cases, he has not been responsible for their treatment. Therefore, the Court finds his opinion of less credibility in this area.

Furthermore, while Dr. Brenner believed the musculoskeletal pain is unrelated to the Lupus and/or the vaccination, Tr. at 48, the following exchange, quoted previously, is particularly instructive:

A He already had Lupus.
Q Now he has Lupus?
A No, he had Lupus then. That's my point.
Q Yes, but he was asymptomatic, aside from the nodules, wasn't he?
A Yes.
Q So wasn't there a significant worsening of symptoms after the Hepatitis B?
A Absolutely.

Tr. at 103-04. So, according to Dr. Brenner, was there a significant worsening of symptoms following the vaccination? "Absolutely." Tr. at 104.

According to the Federal Circuit in Whitecotton, when it comes to significant aggravation, one of the primary questions is whether "the person's current condition constitutes a 'significant aggravation' of the person's condition prior to vaccination" within the meaning of the Vaccine Act. Whitecotton v Secretary of HHS, 81 F.3d 1099, 1107 (Fed.Cir. 1996). The Act, of course, defines significant aggravation as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." §33(4).

The Court finds that Respondent's argument, taken at face value, that Petitioner had a pre-existing though latent condition, entails that Petitioner prevail on the grounds of significant aggravation, particularly when coupled with the opinions of his treating and evaluating physicians, three of whom opined against their interest so to speak as they were employed by the insurance company embroiled in Petitioner's workers' compensation claim, who "are likely to be in the best

position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury,'" Capizzano, 440 F.3d at 1317 (quoting Althen, 418 F.3d at 1280), and who associated the onset of his deteriorating condition with the acute vaccine-related reaction four hours post vaccination, a reaction that, according to Dr. Brenner, was sequella to the vaccination, Tr. at 44, but for which he does not "understand the mechanism" of how "an acute reaction, which is probably allergic mediated, then, in and of itself, lead to chronic muscular/skeletal pain." Says Brenner, "I don't have an explanation for that, because I don't understand the mechanism. It doesn't make sense." Tr. at 43-44.

But according to the Federal Circuit:

> Furthermore, to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims. The Vaccine Act established a federal "compensation program" under which awards are to be "made to vaccine-injured persons quickly, easily, and with certainty and generosity." House Report 99-908, supra, at 3, 1986 U.S.C.C.A.N. at 6344.
>
> The Court of Federal Claims is therefore not to be seen as a vehicle for ascertaining precisely how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others.

Knudsen v. Secretary of HHS, 35 F.3d 543, 549 (1994).

Moreover, as the Court of Federal Claims opined:

> Indeed, one can imagine a hypothetical case where a completely healthy individual receives a vaccine and suffers some condition shortly thereafter. The Special Master may conclude that, based on the entirety of facts--including the petitioner's relative health prior to the vaccine--the petitioner has satisfied his burden of proof. This might be the case if there is an absence of alternative causes apparent in the record or the biologic mechanism that petitioner demonstrates is particularly compelling.

Pafford v. Secretary of HHS, 64 Fed. Cl. at *31.

In fine, Petitioner was a relatively healthy, asymptomatic individual who receives a Hepatitis B vaccination and within four hours suffers what Respondent's expert characterizes as an acute, allergic mediated reaction to that vaccine and who thereafter goes on to develop a cascade of problems, some subjective and others objectively verified by laboratory testing, eventually diagnosed as a connective tissue disorder and from which he is rendered disabled. The Court finds that, for the reasons articulated supra, Petitioner is entitled to compensation on the basis of significant aggravation of a pre-existing condition.

CONCLUSION

The Court finds that Petitioner is entitled to Program compensation. In so doing, the Court would like to remind the parties of its long standing policy on fair and amicable resolution.

The parties shall contact the Court to discuss further proceedings in this case on the topic of damages but are encouraged to begin discussions between themselves; and Petitioner, if he so chooses, is authorized to engage a life care planner.

IT IS SO ORDERED.

Richard B. Abell
Special Master